



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :  
Shuji Saitoh et al. : GROUP ART UNIT: 1641  
Serial No. 09/147,052 :  
Filed: April 5, 1999 : EXAMINER: Ja-Na Hines  
For: NOVEL FUSION PROTEIN,  
GENE THEREOF, RECOMBINANT  
VECTOR BEARING THE GENE  
AND RECOMBINANT VIRUS  
AS WELL AS USE THEREOF

D E C L A R A T I O N

ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D. C. 20231

Sir:

I, Shuji Saitoh, a Japanese Citizen, residing  
at 3-35-8, Yokodai, Isogo-ku, Yokohama-shi, Kanagawa-ken,  
Japan, declare:

That I graduated from Nagoya university with  
a degree in Science in March, 1979, entered NIPPON ZEON  
Co., Ltd. in 1984 and have since then been engaged in  
genetic recombination research;

That I am one of the co-applicants of the above-identified application (hereinafter referred to as the present application);

That I have read and understand the specification of the present application and the office action issued against the present application on February 29, 2000,

That in order to show that the fusion protein of the present invention provides better results than the fusion protein of Saito et al. (WO 94/23019), I conducted a Mycoplasma challenge test of recombinant viruses of Saito et al. in the following manner to obtain the following result:

#### Experiments

The challenge test was conducted in the same manner as in Example 6 of the description of the present application, except for that fNZ7929-67, fNZ7929-66 or fNZ2929XM1, which was disclosed in Examples of Saito et al. and derived from Newcastle disease virus (NDV), was inoculated to SPF chicken.

#### Results

The tracheal lesion score of the chicken inoculated with fNZ7929-67, fNZ7929-66 or fNZ2929XM1 was

shown in the following table. In this connection, criteria to determine tracheal lesion scores is the same as that indicated in Table 2 of the description of the present application.

| Vaccination | Lesion score |                |
|-------------|--------------|----------------|
|             | Average      | Standard Error |
| fnZ7929-67  | 2.02         | 0.20           |
| fnZ7979-66  | 2.41         | 0.17           |
| fnZ2929XM1  | 2.46         | 0.21           |
| None*       | 2.27         | 0.21           |

\*; This data corresponds to that of "None" in Table 3 of the description of the present application.

The above results clearly show that the lesion score of the chicken inoculated with fnZ7929-67, fnZ7929-66 or fnZ2929XM1 is approximately equivalent to that of the non-inoculated chicken, so that fnZ7929-67, fnZ7929-66 or fnZ2929XM1 of Saito et al. is not effective as a vaccine in vivo.

The undersigned declarant declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 21st day of June, 2000.

  
Shuji SAITOH